BraunSolutions®

MAR 6 2009

510(k) Summary
(Per 21 CFR 807.92)

Submitter/Owner:

Noble Anesthesia-Air, Inc.
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Gainesville, Florida 32606

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377 Zane Court,
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Contact Person: Alex Henderson
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Email: alex_henderson@msn.com

Date Prepared: August 25, 2008

Device Name:

Trade/Proprietary Name: Snor-Scope Plus™ and/or Snor-Scope +™ System (Kit)
Common/Generic Name: Electronic Stethoscope
Classification Name: Electronic Stethoscope, Class II (Two)
(21 CFR 870.1875(b), Product Code DQD)

Predicate Devices:

RNK Products Stethoscope (K030446, K072026)
Pishon High Tech Co. Stethoscope (K062481)
Meditron AS Stethoscope (K991367)

Related Accessories: (Kit)

Classification	Description	Class
21 CFR 868.5240	Breathing Circuit (Kit)	I
21 CFR 868.5810	Airway Connector	I
21 CFR 868.5860	Pressure Tubing and Accessories	I
21 CFR 868.1930	Stethoscope Head	I
21 CFR 870.1875	Stethoscope	I

510(k) Summary
Noble Anesthesia-Air
Electronic Stethoscope

Device Description: (Reference Exhibit A, Page 12) Class I ME Device

The Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope System is a kit comprised of the following components: (Guidance IEC60601-1 2005 Sec. 4 "General Requirements" and various other sections, where applicable).

- Audio amplifier module and microphone
- Plastic T-connector / diaphragm coupler assembly (airway adapter)
- Single Plastic coupler (stethoscope adapter)
- Stethoscope Head (standard mechanical acoustic)
- Stethoscope (standard mechanical acoustic)
- Wall charger (UL listed, medical grade) and eight (8) batteries (rechargeable)

A shielded microphone and audio cable, with a 3.5mm plug, connects the microphone/coupler assembly to the amplifier module. The speaker volume may be adjusted on the audio amplifier module to allow comfortable listening levels of breathing sounds passing through the airway circuit for Anesthesia Physicians and Clinical Personnel. A standard stethoscope ear piece may also be used for private listening purposes, although it does not provide the same amplification as in electronic stethoscope mode.

The Snor-Scope Plus T-connector is composed of a plastic diaphragm and connector cap which holds the diaphragm tightly in place. This T-connector serves as an attachment for either the manual stethoscope (without head) or to the electronic stethoscope microphone. The device is not sterile, is outside the surgical field, and is a single-use disposable accessory.

A single plastic medical grade coupler may also be used as an interface between the Snor-Scope Plus microphone and standard stethoscope dual-diaphragm head for the same purpose that would otherwise require an acoustic (non-electronic) stethoscope.

The Noble Anesthesia-Air Electronic Stethoscope provides 20 times greater signal amplitude than a standard acoustic stethoscope. The overall frequency response is 15 – 1500 Hertz. This stethoscope is a stand-alone unit, has no software, and operates using an analog audio system without introducing any signals or energy into the patient or anesthesia breathing circuit.

The Amplifier Module is powered by rechargeable Nickel Cadmium Batteries which can be easily replaced. The charger consists of a medical grade UL listed wall adapter. The batteries and charger are part of the overall packaged kit. The audio amplifier module controls charging which cannot be performed during use of the Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope.

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510(k) Summary
Noble Anesthesia-Air
Electronic Stethoscope

Statement of Intended Use:

The Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope is intended as a diagnostic aid in patient monitoring, diagnostics, and treatment under the same conditions that would otherwise require the use of an acoustic (non-electronic) stethoscope.

In addition, the Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope is also intended for electronically amplifying sounds of evolving obstruction of the upper airway in patients without an endotracheal tube undergoing sedation or general anesthesia by an anesthesia care professional.

It is not intended to be used for diagnosis and treatment by unlicensed, untrained, or unqualified medical persons.

Substantial Equivalence:

Although the Snor-Scope Plus has an additional and unique Indication for Use, the design components and functionality of the Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope are substantially equivalent to the predicate devices listed. The overall effectiveness has been, and continues to be, demonstrated in user testing with Anesthesiologists and Clinicians.

The Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope has the same principles of operation and technological characteristics as the auscultation function of the predicate devices. System analysis and testing have resulted in no new questions concerning safety and effectiveness.

Substantial Equivalence Comparison Chart

	Predicate Devices			**New Device**
Device Name	RNK Products Electronic Stethoscope **K030446, K072026**	Pishon High Tech Electronic Stethoscope **K062481**	Meditron AS Electronic Stethoscope **K991367**	Snor-Scope Plus Electronic Stethoscope
Classification Name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Applicant	RNK Products	Pishon High Tech	Meditron AS	Noble Anesthesia-Air
Frequency Response	20 Hz - 1,500 Hz	20 Hz - 1,500 Hz	20 Hz - 1,500 Hz	20 Hz - 1,500 Hz
Amplification	Up to 20 Times	Up to 20 Times	Up to 18 Times	Up to 20 Times
Heart Rate Display	No	No	No	No
Data Transfer to PC	No	Yes	Yes	No
Volume Control	Variable	12 Step	Variable	Variable
Energy Source	(2) AAA Batteries	(2) AAA Batteries	(4) AA Batteries	(8) AA Batteries
Manual On/Off Button	Yes	Yes	Yes	Yes
Low Battery Indicator	Yes	Yes	Yes	Yes

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510(k) Summary
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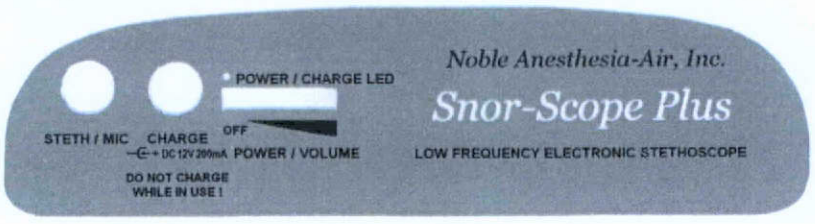
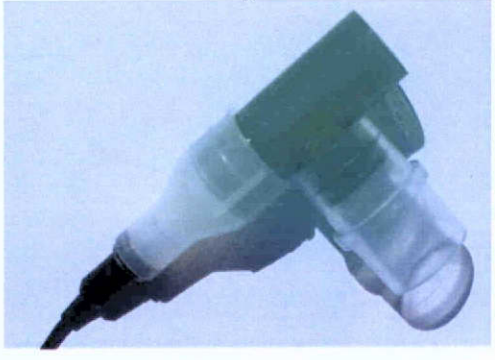
Proposed Labeling: Audio Amplifier –Front (Guidance: IEC60601-1 Sec. 15)

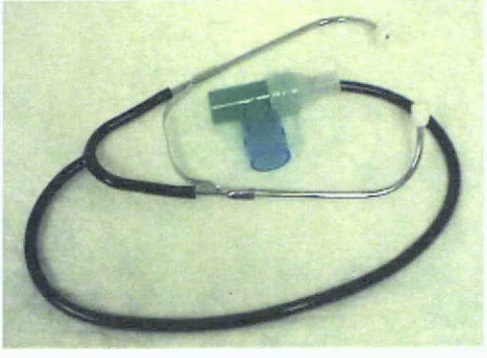


T-Connector Coupler Photos

Electronic Stethoscope



Manual Stethoscope



Amplifier, Microphone, T-Connector

Located on Charger:

CAUTION!
Only Charge Snor-Scope Plus
When unit is off
Unplug charger when not in use

Located on T-Connector:

CAUTION!
Check Air-Way Circuit
For Leaks Prior to Use

Located on Bottom:

SNOR-SCOPE PLUS®
Electronic Stethoscope
SERIAL NUMBER: _____
CAUTION!
FOR USE BY LICENSED ANESTHESIOLOGIST ONLY

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510(k) Summary
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Clinical Assay: (Reference Exhibit B, Page 13)

"Pediatric Sedation Outside of the Operating Room"

SPONSORED BY: Harvard University, San Francisco CA USA
September, 2008.

The data to be presented was gathered during a study that was done while Dr. James P. Noble was in private practice. The formal study involved 10 patients representative of the patient population for which Dr. Noble had cared for over nearly 10 years during the development of his special technique to improve the safety of anesthesia for cosmetic surgery patients. The Snor-Scope Plus, in various stages of its evolution, was an essential part of this technique.

The formal study was approved in 2005 by the Western Institutional Review Board. The identifying information of this study is:

TITLE: The Effects of CPAP on Airway Obstruction in Sedated Spontaneously Breathing Facial Rhytidectomy Patients

PROTOCOL NO.: WIRB Protocol #20050216

SPONSOR / INVESTIGATOR / SITE: Robert N. Cooper, M.D.
201 East Osceola Street
Stuart, Florida 34994 USA

CONCLUSION SUMMARY:

The stridor that was reported in the results was accurately detected by the Snor-Scope Plus. There were no adverse effects or complications.

The Snor-Scope Plus passed inspection by the Biomedical Engineers at Shands Teaching Hospital at the University of Florida under ANSI C63.18-1997 and AAMI TIR 18 Recommendations for EMC / EMI in Healthcare Facilities. Test data is not present in this submission.

Additional clinical study information has not been submitted for the purpose of demonstrating substantial equivalence to legally marketed electronic stethoscopes.

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510(k) Summary
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Safety and Performance: (Guidance: IEC60601-1 2005, where applicable)

The Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope is intended for use outside of the surgical sterile field. The plastic connector couplers are intended as single-use, disposable accessories and are not sterile. The Snor-Scope Stethoscope plastic T-connector coupling assembly isolates the microphone electrically from the acoustic mechanical pick-up diaphragm, anesthesia airway connectors, and the patient. It is part of the fixed port (reused as standard practice) on the anesthesia machine.

The internal speaker and microphone cable are shielded to eliminate Electrical Magnetic Interference. The audio amplifier module, microphone, or cable do not introduce any signals or energy into the patient or anesthesia airway circuit and do not pick-up signals from other medical devices (e.g. Lasers, Telemetry, Electrocautery devices) in the room. The amplifier module plastic casing (double insulated) and all anesthesia coupler / hose components meet UL flammability ratings for medical devices. (Sec. 8 "Protection against Electrical Hazards", Sec. 9 "Protection against Mechanical Hazards" and Sec. 17 "Electromagnetic Compatibility of ME Equipment")

Battery charging is controlled by internal management circuits of the audio amplifier module and is disabled during use. Warning labels indicate that the audio amplifier module must be recharged outside the operating room. The system is not directly connected to 120 VAC wall outlet power during use, and there are no exposed conductive metal parts, thus alleviating any patient or health practitioner shock hazards. (Sec. 8 "Protection against Electrical Hazards")

There is limited skin contact with the patient or medical personnel with respect to the bell diaphragm (standard acoustic stethoscope type), as an approved Class I device. There is no skin contact with the patient or medical personnel at any time, as described under additional Indications for Use. Biocompatibility with respect to ISO10993-Part 1, Biological Evaluation of Medical Devices Part – 1 (G-95-1), does not apply.

Physiological Effects: (Guidance: IEC60601-1 2005 Sec. 8 "Protection against Electrical Hazards")

The patient has no contact with the unit or leads. Therefore, there are no physiological effects concerning Threshold of Perception, Let-Go Current, Respiratory Paralysis, Ventricular Fibrillation, Sustained Myocardial Contraction, or Burns and Physical Injury.

Shock Hazards: (Guidance: IEC60601-1 2005 Sec. 8 "Protection against Electrical Hazards")

The unit chassis and microphone T-connector are made of non-conductive plastic and all leads consist of insulated rubber over shielded wire. Current Leakage to ground is 0.0 mA as the unit is not connected to A-C wall power during operation. There are no exposed metal contacts.

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510(k) Summary
Noble Anesthesia-Air
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Non-Clinical Testing: (Reference: T-Connector Assembly Test Protocol, Page 10)

Under typical use as a standard acoustic stethoscope, the diaphragm head is the only component that routinely comes in contact with the patient or health practitioner. There is no possibility of current leakage, as the microphone and cable is shielded and electrically isolated by the interface coupling assembly and rubber stethoscope hose. The same holds true for the T-connector / diaphragm coupler components in the anesthesia airway circuits (conveying non-flammable gases) as they never come into to contact with the patient or health practitioner.

Internal shielding provides minimal electromagnetic field or radiated emission measurements. Pressure tests were conducted on a random sample of T-connector diaphragm component assemblies. Current leakage test during operation yielded no results.

Environment: System is intended for use at ambient room temperature 25 Deg. C. (Guidance IEC60601-1 2005 Sec. 5 "General Requirements for Testing ME Equipment")

Conclusions:

The indications for use as described is consistent with the labeling for electronic stethoscopes legally marketed in the United States under FDA regulation 21 CFR 870.1875(b) for this type of device.

In addition, operation is also consistent with the general operating principles for electronic stethoscopes and would have minimal potential for any adverse health concerns as it does not interrupt anesthesia airway operation. The passive T-connector has been specifically designed to have no effect on the Anesthesia Devices to which it is attached and, more importantly, the patient.

The Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope does not fall under FDA Regulation 21 CFR 898.12 Performance Standards and does not emit vibrations or emissions that would affect the patient or other medical devices as listed under FDA Regulation 21 CFR 1000.15 Radiological Health for "Sound Amplification Equipment".

It is possible, but not likely, that the T-connector diaphragm might rupture and cause an anesthesia circuit leak. This occurrence would be detectable by routine pressure checks of the breathing circuit and by listening for a leak over the connecting port of the stethoscope.

The Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope is a reliable monitor to detect an evolving obstruction of the upper airway. Detection of stridor should trigger the early adjustment of flow rates and pressure within the breathing circuit until airway obstruction and its telltale stridor is eliminated.

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510(k) Summary
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Drop Test Performance: (Guidance: IEC60601-1 2005 Sec. 5 "General Requirements", Sec. 9 "Protection against Mechanical Hazards" and Sec. 15 "Construction of ME Equipment")

AXIS: X: Top (Speaker) Down
Y: Front (Control/Inputs) Down
Z: Sideways/Angled Down (Corner)

CRITERIA:

1. Perform three (3) separate drop tests for each axis from a height of three (3) feet onto a hard, uniform surface (concrete floor). Note external damage, if any, on chart.
2. Perform function test. Note failures on chart.
3. Open case and note any internal damage, if any, on chart. Document with photos.
4. If any major external or internal damage is indicated – route to QC for Root-Cause Analysis.

Note: If no structural failures indicated, enter "None". If no functional failures indicated, enter "Passed".

SUMMARY DATA

SnorScope Plus	X Axis Notes	Y Axis Notes	Z Axis Notes	Functional Test	
	TEST 1:	TEST 2:	TEST 3:	UNIT:	BATTERIES:
Unit #1 S/N: 0103	Scratched	None	Dent - Corner	Passed	Passed
Unit #2 S/N: 0107	None	Scratched	Hairline Crack -Corner	Passed	Passed
Unit #3 S/N: 0124	None	None	Dent - Corner	Passed	Passed
Comments:				Disposition: Continue tests until final release. Certified by:	
No Internal Damage.	Volume Control OK.	Connectors OK.	Speaker OK. Crack did not affect function	James P. Noble, M.D. Date: 01/12/2009	

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510(k) Summary
Noble Anesthesia-Air
Electronic Stethoscope

T-Connector Assembly Test Protocol:

Pressure tests are conducted on random T-Connector assemblies in the following manner:

1. The connector is tested at the absolute extremes of pressure ventilation capable of being generated by a typical anesthesia ventilator:

Machine: Datex-Ohmeda AVANCE S5	
Maximum Positive End-Expiratory Pressure ("PEEP")	= 30 cm of water
Maximum Added Positive Pressure Ventilation	= 60 cm of water
Total Pressure	= 90 cm of water

2. The diaphragm of the Stethoscope-Connector cannot fail after being subjected to 25 cycles of 90 cm of water pressure of the ventilator, i.e., the diaphragm is not ruptured and no leak is produced.

Discussion:

☑ 90 cm of water pressure is about double the extreme of pressures that may be used clinically.

☑ The label on the packaging will include a caution to check the connector for leaks prior to starting an anesthetic and during the anesthetic should a leak be suspected in the breathing circuit.

James P. Noble, M.D.

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510(k) Summary
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Hazardous Conditions Test Protocol - Liquid:
(Guidance: IEC60601-1 2005 Sec. 4 "General Requirements", Sec. 8 "Protection against Electrical Hazards" and Sec. 16 "ME Systems")

CRITERIA: Random Test

1. NORMAL TEST:
   Perform current-leakage test on five (5) amplifier module, microphone, and T-connector assemblies – attach meter between microphone/T-connector body and ground (-).
   a. With charger unplugged
   b. With charger plugged in
   Record results for each unit on the chart.

2. DESTRUCTIVE TEST:
   Perform current-leakage test on ten (10) amplifier module, microphone, and T-connector assemblies – attach meter between microphone/T-connector body and ground (-).

   First five (5) units:
   a. With charger unplugged; pour sodium chloride, 0.9% USP, on top of unit and on down cord to microphone/T-connector assembly.
   b. Open case and check fuse continuity.
   Record results for each unit on the chart.

   Second five (5) units:
   c. With charger plugged in; pour sodium chloride, 0.9% USP, on top of unit and on down cord to microphone/T-connector assembly.
   d. Open case and check fuse continuity.
   Record results for each unit on the chart.

Send units to QC Dept. to be quarantined / scrapped. Tag: "Engineering Evaluation"

Discussion: (Guidance: IEC60601-1 2005 Sec. 11 "Protection against other Hazards")

- Test results from these tests have indicated that there is no current leakage, with or without the battery charger plugged in, under normal operating conditions. The unit case and microphone/T-connector assembly impedance is infinite.

- During destructive testing, there was slight current leakage between 0.02 mA – 0.03 mA with the battery charger plugged in (battery charger cannot be used during normal acoustic operation). If the internal PC board power components were shorted by the sodium chloride solution, the micro fuse (Fast Acting, 750 mA, One Time) indicated no continuity (open circuit) and leakage current was 0.0mA. Without the battery charger plugged in, current leakage was between 0.01 mA – 0.02 mA on average. Same micro fuse conditions were found (open circuit) if power components were shorted by the sodium chloride solution. Fuse open time was approximately 2 – 3 seconds as indicated by 0.0 mA current leakage measurements.

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510(k) Summary
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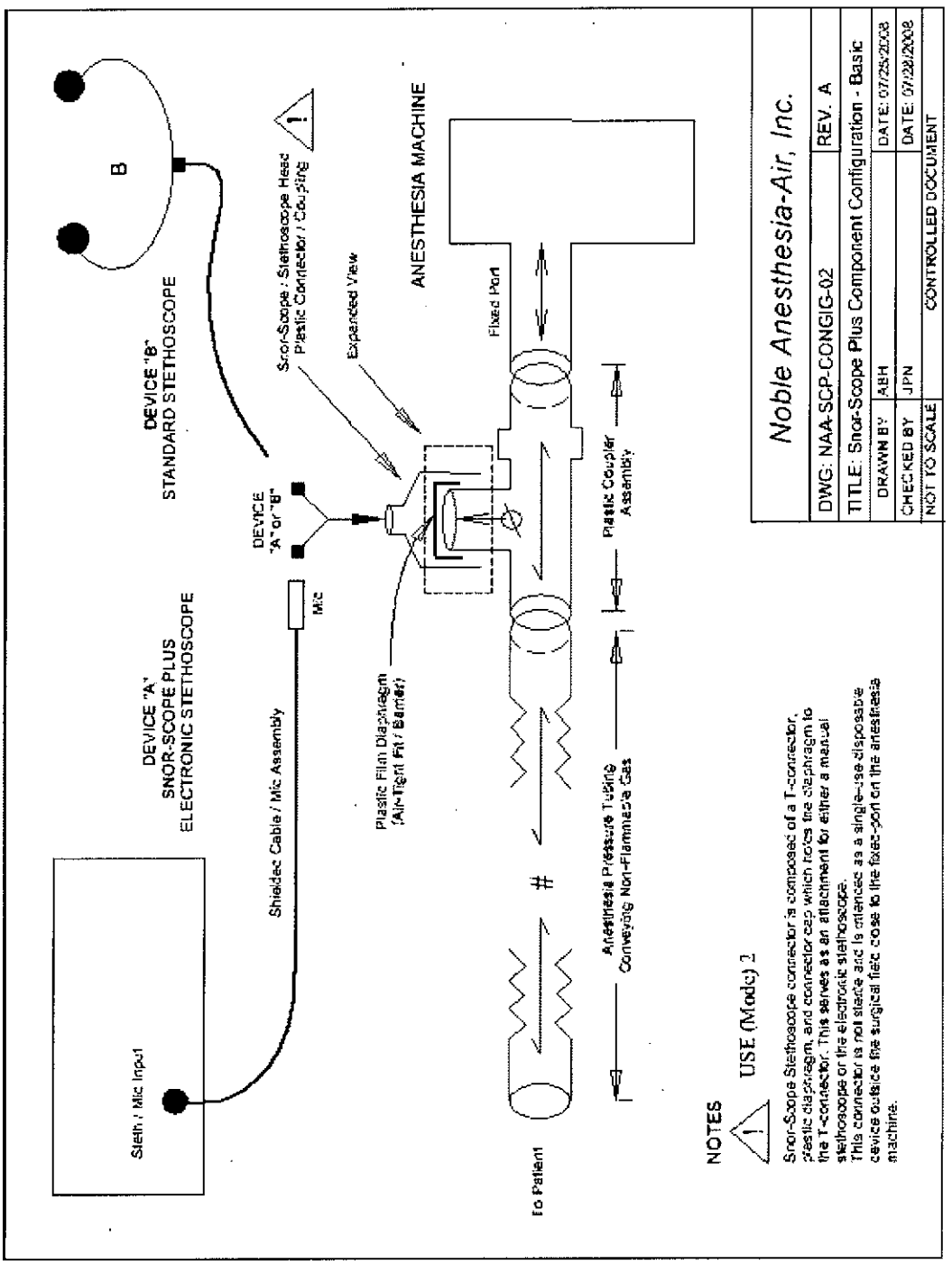
EXHIBIT A – Configuration Drawing (Full Size Copy, Page 12(a))



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510(k) Summary
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EXHIBIT B – Clinical Presentation Slide (Full Size Copy, 13(a))

Non-Invasive Nasally-Applied Positive Airway Pressure Prevents Upper Airway Obstruction and Facilitates Adequate Spontaneous Respiration During Mild, Moderate and Deep Sedation, and General Anesthesia

JP Noble, RN Cooper†*
Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida*;
Water's Edge Surgery Center, Stuart, Florida†

Introduction

The syndrome of narcogenic obstructive respiration (SNOR) describes the upper airway obstruction that tends to occur during the induction of anesthesia.[1,2] Continuous positive airway pressure (CPAP) has been used in anesthetized children.[3] We hypothesized that transcutaneous CO_2 determinations would help to confirm that nasal positive airway pressure applied to the mildly sedated patient would safely preserve spontaneous respiration as sedation was deepened to general anesthesia. This study in adult patients is presented as "proof of concept" for application in pediatric patients.

Methods

After Western Institutional Review Board approval and informed consent, ten consecutive cosmetic surgery patients were studied. Data collected were primarily designed to demonstrate the airway constricting effect of tightening the superficial musculo-aponeurotic system (SMAS) during rhytidectomy. General anesthesia was provided using various combinations of isoflurane, propofol, dexmedetomidine and fentanyl. The airway was managed by a NVA® (Nasal Vestibule Airway), a pressure-sealing nasal cannula connected to a standard anesthesia circuit. The pop-off valve and gas flows were adjusted to achieve an airway pressure that would eliminate the stridulous sounds of airway obstruction. All patients were allowed to breathe spontaneously throughout the procedure. Patient monitors included a dial pressure gauge, a SNOR-SCOPE® (circuit stethoscope), and a transcutaneous CO_2 monitor.

Results

Surgery times ranged from 84 to 380 minutes for combined procedures that included rhytidectomy. Two patients with body mass indices of 34 and 38 had liposuction in the prone position. Respiratory rates ranged from 13 to 26 breaths per minute. Arterial pCO_2 derived from transcutaneous measurements ranged from 35 to 49 mm Hg. Oxygen saturations were consistently greater than 92% using an oxygen concentration of 30% or less. The SMAS phase of the rhytidectomy caused stridor in 5 patients which was relieved by increasing airway pressure. In 3 patients airway pressure increased after SMAS without stridor or adjustment as if an increment in airway constriction also increased the pressure needed for gas to escape the pharynx. One patient had no change after the SMAS.

AIRWAY PRESSURE WORKS IN THE NEWBORN AND OTHER "OBLIGATE" NASAL BREATHERS WHERE THE AIRWAY ANATOMY IS DEDICATED TO RESPIRATION AND MOST RESISTANT TO OBSTRUCTION

AIRWAY PRESSURE WORKS IN THE ADULT WHERE THE MATURED AIRWAY ANATOMY SHARES RESPIRATION WITH SWALLOWING AND SPEAKING AND HAS BECOME SUSCEPTIBLE TO OBSTRUCTION

THEREFORE, AIRWAY PRESSURE SHOULD WORK IN CHILDREN WHERE THE AIRWAY ANATOMY IS AT AN INTERMEDIATE STAGE OF MATURATION, BUT STILL MORE RESISTANT TO OBSTRUCTION

https://www.brianpalmerdds.com

Patient number	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Pre-SMAS Pressures											
Inspiratory (cmH2O)	3	2	1	4	4	15	5	9	4	7	2
Expiratory (cmH2O)	4	5	4	5	7	10	4	9	7	14	4
Post-SMAS Pressures											
Inspiratory (cmH2O)	4	8	6	16	7			8	12	16	7
Expiratory (cmH2O)	12	12	8	15	16	NO	NO	9	16	20	14
STRIDOR post SMAS	YES	YES	NO	NO	YES	NO	NO	NO	NO	YES	YES
CO_2 Measured	45	58	44	48	41	46	48	58	49	56	44
CO_2 Corrected to arterial	36	47	35	39	35	39	39	49	46	46	35
Respiratory Rate	16	26	14	16	21	24	21	13	15	26	16

Notes
1 Stridor after SMAS was eliminated by adjusting flow rates and pressures.
2 Airway pressure increased after SMAS without stridor or adjustment.
3 Returned to surgery and pressures were about the same as ending pressures from previous surgery.
4 An LMA was inserted in preparation for a tracheostomy prior to completion of SMAS.
5 Exhibiting no changes with SMAS.

Discussion

We conclude that, even under deep sedation and general anesthesia, the spontaneously breathing adult patient can breath adequately as long as upper airway obstruction is prevented by titrated nasal positive pressure and the respiratory rate is not depressed below 13. Initial experience in pediatric patients (MRI, endoscopy, and dressing change procedures) indicates that pediatric patients have an airway that is well-managed by this technique and, more consistently so than adult patients.

References

1. Cooper R, Noble J: Managing narcogenic obstructed respiration in the aesthetic surgery patient. Aesthet Surg J 1999; 19:485-486.
2. Liang Y, Kimball W, Kacmarek R, Zapol W, Jiang Y: Nasal ventilation is more effective than combined oral-nasal ventilation during induction of anesthesia in adult subjects. Anesthesiology 2008; 108:998-1003
3. Suresh D, Purdy G, Wainwright A, Flynn P: Use of continuous positive airway pressure in paediatric dental extraction under general anesthesia. Br J Anaesth. 1991 Feb;66(2):200-4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2009

Noble Anesthesia Air Inc.
c/o Mr. Alex Henderson
Braun Solutions
377 Zane Court
Elizabeth, CO 80107

Re: K082528
Trade Name: Snor-Scope Plus Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: February 23, 2009
Received: February 26, 2009

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082528

Device Name: Snor-Scope Plus Electronic Stethoscope

Indications for Use:

The Noble Anesthesia-Air Snor-Scope Plus™ Electronic Stethoscope is intended as a diagnostic aid in patient monitoring, diagnostics, and treatment under the same conditions that would otherwise require the use of an acoustic (non-electronic) stethoscope.

In addition, the Noble Anesthesia-Air Snor-Scope Plus Electronic Stethoscope is also intended for electronically amplifying sounds of evolving obstruction of the upper airway in patients without an endotracheal tube undergoing sedation or general anesthesia by an anesthesia care professional.

It is not intended to be used for diagnosis and treatment by unlicensed, untrained, or unqualified medical persons.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 3/5/09
Division of Cardiovascular Devices
510(k) Number K082528